COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 17-XI-2004
C(2004)4487

NOT FOR PUBLICATION

COMMISSION DECISION

of 17-XI-2004

amending the marketing authorisation for "TARGRETIN - bexarotene", a medicinal product for human use, granted by Decision C(2001)818

(Text with EEA relevance)

ONLY THE ENGLISH TEXT IS AUTHENTIC

COMMISSION DECISION

of 17-XI-2004

amending the marketing authorisation for "TARGRETIN - bexarotene", a medicinal product for human use, granted by Decision C(2001)818

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products[1],

Having regard to Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93[2], and in particular Article 4(5) thereof,

Having regard to the notifications submitted by Ligand Pharmaceuticals UK Ltd under Article 4(1) of Regulation (EC) No 1085/2003,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[3], as amended by Directive 2002/98/EC[4] and by Directive 2003/63/EC[5], and in particular Article 61(3) thereof,

Whereas:

(1) The European Agency for the Evaluation of Medicinal Products has acknowledged the validity of the type IA notifications between 23 March 2004 and 23 September 2004, informing the marketing authorisation holder accordingly, and has prepared a list of these notifications. Pursuant to Article 4(5) of Commission Regulation (EC) No 1085/2003, the mentioned variations take

[1] OJ L 214, 24.8.1993, p. 1. Regulation as amended by Commission Regulation (EC) No 649/98 (OJ L 88, 24.3.1998, p. 7).
[2] OJ L 159, 27.6.2003, p. 24.
[3] OJ L 311, 28.11.2001, p. 67.
[4] OJ L 33, 8.2.2003, p. 30.
[5] OJ L 159, 27.6.2003, p. 46.

effect from the date of the notification of validation by the European Agency for the Evaluation of Medicinal Products.

(2) The marketing authorisation should be updated, and Decision C(2001)818 of 29 March 2001 amended accordingly.

(3) In addition, Ligand Pharmaceuticals UK Ltd has submitted under Article 61(3) of the Directive 2001/83/EC, notification(s) for changes to an aspect of the labelling or/and the package leaflet. The European Medicines Agency has accepted these notifications, informing the marketing authorisation holder accordingly, and has prepared a list of these notification(s).

(4) For the sake of clarity and transparency, it is advisable, following the amendment of part or parts of the annexes to a marketing authorisation, to provide for consolidated versions thereof. For this reason, a full set of annexes concerning the marketing authorisation for the medicinal product "TARGRETIN - bexarotene" is attached to this decision.

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2001)818 is amended as follows:

1) The list of notifications for minor variations between 23 March 2004 and 23 September 2004 is added to the updated marketing authorisation.

Application number	Scope (EU numbers affected)
EMEA/H/C/326/IA/06	5 (IA) (EU/1/01/178/001)

2) The list of notifications under article 61(3) of Directive 2001/83/EC is added to the updated marketing authorisation

Application number	Annex (EU numbers affected)
EMEA/H/C/326/N/07	IIIAB (EU/1/01/178/001)

3) Annex II is replaced by the text set out in Annex II to this Decision;

4) Annex III is replaced by the text set out in Annex III to this Decision.

Article 2

This Decision is addressed to Ligand Pharmaceuticals UK Ltd, Innovis House, 108 High Street, Crawley, West Sussex RH10 1BB, UNITED KINGDOM.

Done at Brussels, 17-XI-2004

For the Commission
Olli REHN
Member of the Commission